UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/530,818	01/09/2002	David R. Elmaleh	MGA-004.25	2433

25181 7590 02/05/2003

FOLEY HOAG, LLP
PATENT GROUP, WORLD TRADE CENTER WEST
155 SEAPORT BLVD
BOSTON, MA 02110

EXAMINER
JONES, DAMERON

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 02/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/530,818	ELMALEH ET AL.	
	Examiner	Art Unit	
	D. L. Jones	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 January 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *8* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

APPLICANT'S INVENTION

1. Applicant's invention is directed to compositions and uses thereof comprising an agent having a radionuclide and a targeting agent with a plaque formation component.

Note: Claims 1-18 are pending.

DOUBLE PATENTING REJECTION

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1-11 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims1, 2, 6-9, 12-14, 16, 17, 31, 33, and 35 of U.S. Patent No. 6,299,857. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to compositions and uses thereof wherein the composition comprises a radionuclide and cardiovascular targeting agent. The claims differ in that the patented claims are directed specifically to a targeting moiety comprising a residue of a nucleotide polyphosphate precursor.

102 REJECTION

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in-
> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

5. Claims 1-11 are rejected under 35 U.S.C. 102(e) as being anticipated by Edwards et al (US Patent No. 5,744,120).

Edwards et al disclose radiopharmaceuticals and kits thereof that are useful as imaging agents for diagnosing cardiovascular disorders, infectious disease, and cancer.

The radiopharmaceuticals comprise phosphine or arsine ligated technetium-99m labeled hydrazine or diazino modified biologically active molecules that all an image to be obtained (see entire document, especially, abstract; column 3, lines 1-16; column32, lines 25-40; columns 32-33, bridging paragraph). In addition, Edwards et al disclose (1) an embodiment wherein the radiopharmaceutical comprises a transition metal radionuclide, a transition metal chelator, a biologically active group conjugated to the chelator, a first ancillary ligand, a second ancillary ligand, and optionally a linking group (column 3, lines 25-32; columns 29–31, Examples 1-10). (2) Likewise, another embodiment is directed to visualizing sites of platelet deposition in a subject by radioimaging (column 12-13, bridging paragraph). The agents may be used for diagnosis of thromboembolic disorders or atherosclerosis. In such instances , thrombus, platelet binding or atherosclerotic plaque binding peptides may be utilized (column 22, lines 9-30; column 33, lines 28-57). (3) Possible radionuclides include 99Tc, 186Re, and 188Re (column 23, lines 59-60).

Thus, both Applicant and Edwards et al disclose compositions and uses thereof wherein the composition comprises a radionuclide and a cardiovascular targeting moiety.

103 REJECTION

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 12-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards et al (US Patent No. 5,744,120).

Edwards et al (see discussion above) fails to disclose a specific kit example wherein comprising a radionuclide and cardiovascular targeting moiety.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to generate a kit comprising a radionuclide and cardiovascular targeting component based on the teaching of Edwards et al. In particular, in column 27, lines 50-61, Edwards et al disclose that kits may be generated with their invention such that they comprise a sterile, non-pyrogenic mixture of a compound encompassed by their invention, two ancillary ligands, and optionally a reducing agent such as stannous chloride (column 20, lines 30-32; column 13 – column 15, line 2). In addition, it should be noted that possible ancillary ligands include glucoheptonate, gluconate, tartrate, and mannitol (columns 22-23, bridging paragraph). Hence, it would have been obvious to generate a kit as set forth in Applicant's claims.

SPECIFICATION

8. This application filed under former 37 CFR 1.60 lacks the necessary reference to the prior application. A statement reading "This is a 371 of Application No. PCT/US98/18685, filed 9/8/98." should be entered following the title of the invention or

as the first sentence of the specification. Also, the current status of all nonprovisional parent applications referenced should be included.

Note: It is duly noted that Applicant refers to Application Serial No. 08/925,213 in the declaration, but has not incorporated the application into the continuing data.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (703) 308-4640. The examiner can normally be reached on Mon.-Fri. (alternate Mon.), 6:45 a.m. - 4:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose' Dees can be reached on (703) 308- 4628. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

D. L. Jones
Primary Examiner
Art Unit 1616

January 30, 2003